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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/145, 1/02, 1/14 — A1

(11) International Publication Number: **WO 96/14893**

(43) International Publication Date: 23 May 1996 (23.05.96)

(21) International Application Number: PCT/SE95/01344

(22) International Filing Date: 13 November 1995 (13.11.95)

(30) Priority Data:
9403910-4 14 November 1994 (14.11.94) SE

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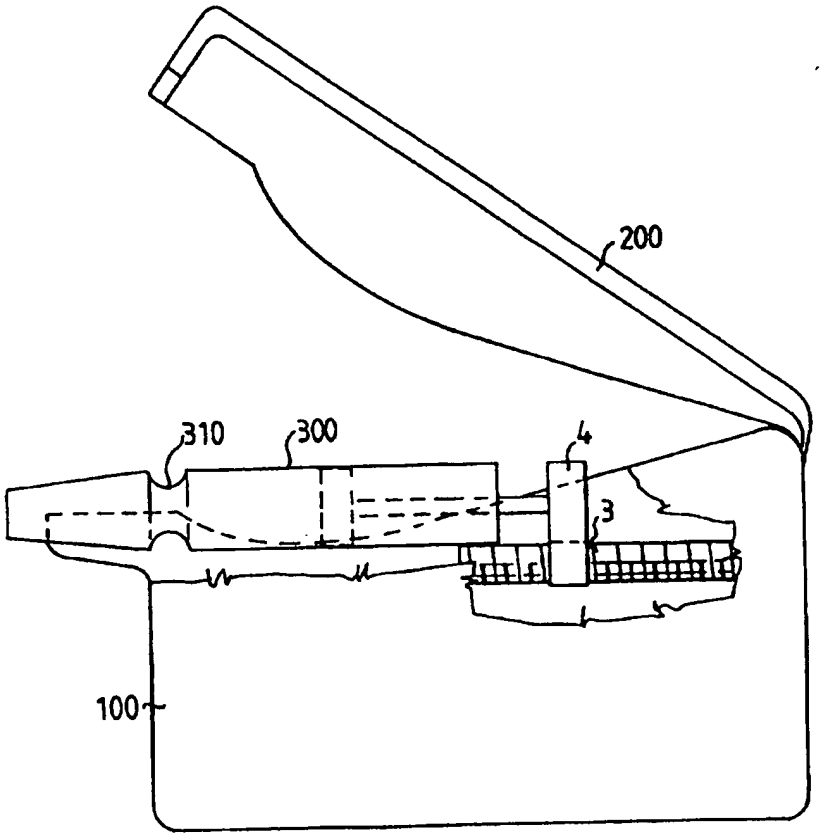
(81) Designated States: AL, AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, LS, MW, SD, SZ, UG).

Published
With international search report.
With amended claims.

(54) Title: AN INFUSION AND MICRODIALYSIS PUMP

(57) Abstract

An infusion and microdialysis pump comprises a casing (100, 200) and an insertable cylinder and plunger (300) of the injection syringe type. Seated on the plunger rod is a runner means (4) which runs on a motor-driven screw (3), thereby to cause the plunger to dispense fluid.



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AN INFUSION AND MICRODIALYSIS PUMP

The present invention relates to an infusion and microdialysis pump of the kind in which a plunger pump in the form of an injection syringe can be fitted in a casing, which includes a motor and drive means connected thereto, wherein the plunger can be moved in the pump chamber and therewith gradually press-out fluid for infusion and microdialysis purposes. More specifically, the invention relates to an infusion and microdialysis pump of the kind defined in the preamble of the following Claim 1.

Such devices are known and commercially available. Equipped with present-day electronic control devices, these devices are able to perform a large number of tasks, such as to inject into patients appropriately measured quantities of insulin or morphine, as required by the patient. Such arrangement are sufficiently small to be connected comfortably to the patient or carried comfortably thereby, and can therewith be used for microdialysis.

The price paid for the smallness and ease of handling of such devices, however, is that it is difficult and troublesome to fit the actual syringe. This difficulty can be tolerated, if necessary, when the device is filled and put in order clinically or polyclinically by experienced and trained personnel, but proves troublesome when a patient or relative has to fill and put the device in order in his or her own home. An object of the present invention is therefore to provide an infusion and microdialysis pump of the kind defined in the introduction where charging and insertion of a syringe into the casing can be effected without requiring particular expertise or skill.

These and other objects and advantages are achieved with an inventive infusion and microdialysis pump having the features

set forth in the characterizing clause of Claim 1. Preferred embodiments of the invention are set forth in the depending Claims.

In accordance with the invention, a syringe, preferably a disposable syringe, shall be capable of being fitted easily into a casing and connected to a motor-driven screw and kept in place by means of a lid, preferably a hinged lid, placed over the syringe. This will ensure that the syringe pusher will come into positive thread engagement with the screw, irrespective of the volume of fluid contained in the syringe. However, the strength of this thread engagement is not sufficiently great to prevent screw engagement being released by virtue of the elasticity of the runner should the screw be rotated to an extent greater than the length of stroke available in the syringe. The runner is preferably made of plastic, and can be made integral with the outer end of the pump plunger or may have the form of a separate component which can be fastened to said end.

The syringe has provided adjacent its outlet orifice a recess or like means which accommodates a bead in the injection position of the casing. When fitting the syringe into the casing, the syringe is placed with the recess against the bead, wherewith the rear part of the syringe rests inclined against a spring device. As a pivotal lid is then swung down over the syringe, the syringe will be moved around the bead to a position in which it lies parallel with the screw under the action of the spring device, so that the rearwardly seated runner on the pusher will be pressed down into a running position on the screw. The two legs of the runner press against the sides of the screw, and the serrated or grooved side of the runner will engage the screw over six-thread lengths, for instance.

In the case of a right-hand screw, it is suitable for the left-hand side of the runner to be in engagement with the

screw, as seen in the outwardly projecting direction of the syringe, which causes the transverse forces that are exerted as the screw rotates and which are due to the inclination of the grooves and the threads will tend to cause the syringe to be drawn inwards and thus not outwards towards the lid.

The drive arrangement is designed as a casing for accommodating the pump chamber and a plunger, with a threaded screw connected to an electric, battery-operated motor, wherein the plunger rod extends beyond the pump chamber and carries a forked device which is open at right angles to the plunger axis and which can be caused to clamp resiliently around the screw, wherein at least one of the inwardly facing sides of the fork means has a grooved pattern whose periodicity coincides generally with the pitch of the screw and which is inclined in relation to the direction of plunger movement, such as to coincide with the slope of the screw threads on that side thereof against which the inwardly grooved side of the fork means resiliently abuts. It is preferred that only one side of the fork means is grooved, since the function is then retained even with less accurate centering between screw and fork means. The fork means is preferably made of plastic, for instance Delrin. The screw is preferably made of metal, and even more preferably of steel.

The invention will now be described in more detail with reference to a non-limiting embodiment thereof and also with reference to the accompanying drawings.

Figure 1 illustrates schematically and partly in cross section a pump and an inserted syringe inserted;
Figure 2 is a block schematic of a microdialysis pump;
Fig. 3 is a sectional view of a casing with drive means for housing a pump chamber of the injection syringe kind and corresponding to a design illustrated in Fig. 2.
Fig. 4 illustrates a running nut which is intended to be fitted to the plunger rod of an injection syringe.

Figure 5 is a cross sectional view taken on the line V - V in Fig. 4.

Shown very schematically in Figure 1 is a casing 100 which has a pivotal lid 200 and in which a syringe 30 is inserted and firmly held through the medium of a groove 310 therein. As will be described in more detail below, the plunger of the syringe can be moved by means of the screw indicated in in the Figure.

The principle illustration in Fig. 2 shows the active components of a microdialysis pump, and a drive motor 1 which drives a screw 3 through the medium of a transmission 2. The screw is straddled by an open nut 4, as described in more detail below, which is fastened to (or made integral with) the plunger rod of a pump corresponding to a syringe or the like 6. The power source has the form of a battery which is controlled by a microcontroller 8 so as to deliver electric current to the motor 1, via a motor drive unit 9. The motor has a through-extending shaft and carries on the end thereof distal from the transmission gearing a code wheel 10 provided with dark and light stripes (not shown) which are sensed by an opto-sensor 11 (light source and light sensor in combination), which signals rotation of the motor to the microcontroller 8 via an opto-logic means.

As will be seen from the cut-away view shown in Fig. 3, the motor 1, the code wheel 10, the gearing and the screw 3 and the battery (7) are all mounted in a housing 20. Remaining components are mounted on the circuit card 21 indicated in the Figure. Although not shown, an upper part is pivotally mounted at 22, wherein a disposable injection syringe provided with a "straddle nut" 4 can be fitted and clamped beneath the lid with the outlet end 13 of the syringe lying in an opening 23 and the plunger rod connected for translatory movement upon rotation of the screw 3.

This simple arrangement is made possible by using a nut 4, shown in more detail in Figs. 4 and 5, which includes a U-shaped recess whose one U-leg has a screw-thread 30 cut thereon, wherein the distance between the legs is adapted to the thread on the screw 3.

This simple arrangement is made possible by using a nut 4, shown in more detail in Figs. 4 and 5, which includes a U-shaped recess whose one U-leg has a screw-thread 30 cut thereon, wherein the distance between the legs is adapted to the screw-thread of the screw 3.

In the case of one embodiment, the screw measures M5 x 0.5 in accordance with SMS 1701, and the distance between the U-legs prior to cutting the thread is 4.5 mm. The straight cut threads 30 on the U-leg suitably define an angle of 1.95° to the cross direction of the nut. The nut may suitably be made of a plastic material, such as Delrin.

In the illustrated embodiment, the motor 1 is built together with a conventional gearbox (not shown) so as to obtain a total ratio of 108:1 together with the gearing 2. When using a conventional disposable syringe (3 ml), the syringe will dispense 0.5 ml of fluid with each rotation of the motor. The screw has a pitch of 0.5 mm and 1/108 of a full rotation of the motor will thus result in a translation of about 4 µm. Since the motor always rotates in one and the same direction, any gaps that are present will have only a negligible effect.

When using a motor designed for a nominal 12 V, it is possible to obtain a suitable feed speed with a 4 V battery, wherein one revolution of the motor will take about one-tenth of a second. When the device is used intermittently and the motor has a speed of one revolution per minute, battery consumption will be so low as to enable a battery to last for fifteen calendar days. However, the investigation period is seldom longer than three to five calendar days.

When inserting a microdialysis catheter, it is necessary to undertake a filling and flushing period, which, e.g., may involve the discharge of 100 µl of fluid at a rate of 15 µl per minute and thus with one motor revolution each other second. Furthermore, all transmission gaps and clearances will be leveled out during this time period. In the following sampling period, fluid is discharged at one revolution per minute, thus in an intermittent quantity of 0.5 µl.

This example relates to a microdialysis catheter having an effective volume of 0.5 µl or negligibly thereabove. When other microdialysis catheters are used, the pump must be adapted accordingly, since the concept is to replace the fluid in the active part of the catheter on each occasion, with no surplus fluid being pressed through and therewith diluting the sample solution. It can be mentioned that individual sample volumes are normally collected during successive time periods, for instance time periods of 15 min., 30 min. or 1 hr., depending on the speed at which, for instance, metabolic developments change such as changes in the sugar values of diabetics or other changes. In other cases, the pump may be used to deliver substances to a patient, and this example should not therefore be considered all-inclusive.

It will be noted that the arrangement shown in the cut-away view of Figs. 1 and 3 is roughly to scale, and it will therefore be readily seen that the arrangement can be carried easily by a patient, and that the patient will experience no appreciable discomfort and that said arrangement can be used in any situation whatsoever and even when taking working samples. The person skilled in this art will understand that the entire arrangement can be attached to the body of the patient with the aid of a strap or with the aid of adhesive tape.

The person skilled in this art will understand that the use of the device to deliver liquids and fluids to patients is highly versatile, in hospitals, polyclinics and in the home.

CLAIMS

1. An infusion and microdialysis pump comprising a casing, a syringe having a pump chamber and a plunger mountable in the casing, wherein the forward part of the pump chamber can be attached to the casing with a dispensing line projecting therefrom, and further comprises an electric motor fitted in the casing, a reduction gear connected to the motor, a screw coupled to an output shaft of the reduction gear, and a pusher means which moves along the screw as the screw rotates, such as to move the plunger in the pump chamber, **characterized** in that the pusher means is connected to the plunger and includes a runner which can be placed against the screw and which includes a surface that has grooves complementary to the thread of said screw.

2. A pump according to Claim 1, **characterized** in that the casing has a pivotal lid which when open exposes a syringe position which includes at one end a semi-circular bead for accommodation in a recess in the pump chamber of said syringe, close to the outlet orifice of said chamber.

3. A pump according to Claim 2, **characterized** in that the syringe position also includes a spring means which when the syringe is inserted into the casing holds the syringe positioned obliquely with its rear end slightly raised, wherein as the pivotal lid is lowered said lid functions to press down the rear end of the syringe against the force of the spring means and therewith press the runner into a running position on the screw.

4. A pump according to any one of the preceding Claims, **characterized** in that the screw is disposed along a line that extends parallel with the direction of plunger movement in the fitted syringe and is offset in relation to the centre line of said plunger.

5. A pump according to any one of Claims 1-3, characterized in that the screw is disposed generally along a centre line of the fitted syringe.

6. A pump according to any one of the preceding Claims, characterized in that the runner includes two mutually facing, generally flat and mutually parallel surfaces of which one has ridges and troughs whose periodicity corresponds to the pitch of the screw-thread and an inclination corresponding to the tangential direction of the screw-thread, whereas the other surface lacks ridges and troughs.

7. A pump according to Claim 2 and Claim 5, characterized in that the surface provided with ridges and troughs is so adapted and chosen in relation to the screw-thread, that the component of force which acts on said surface perpendicular to the direction of the screw as it rotates in the pump emptying direction is directed such as to move the syringe inwards and not towards the lid.

AMENDED CLAIMS
[received by the International Bureau on 10 April 1996 (10.04.96); original claims 1 and 2 amended; remaining claims unchanged (2 pages)]

1. An infusion and microdialysis pump comprising a casing (20), a syringe (6) having a pump chamber and a plunger mountable in the casing, wherein the forward part of the pump chamber can be attached to the casing with a dispensing line projecting therefrom, and further comprises an electric motor (1) fitted in the casing, a reduction gear (2) connected to the motor, a screw (3) coupled to an output shaft of the reduction gear, and a pusher means which moves along the screw as the screw rotates, such as to move the plunger in the pump chamber, **characterized** in that the pusher means (4) is joined to the plunger and includes a rider which can be placed on to the screw and which includes a surface that has grooves complementary to the thread of said screw.

2. A pump according to Claim 1, **characterized** in that the casing has a pivotal lid (200) which when open exposes a syringe position which includes at one end a semi-circular bead for accommodation in a recess in the pump chamber of said syringe, close to the outlet orifice of said chamber.

3. A pump according to Claim 2, **characterized** in that the syringe position also includes a spring means which when the syringe is inserted into the casing holds the syringe positioned obliquely with its rear end slightly raised, wherein as the pivotal lid is lowered said lid functions to press down the rear end of the syringe against the force of the spring means and therewith press the runner into a running position on the screw.

4. A pump according to any one of the preceding Claims, **characterized** in that the screw is disposed along a line that extends parallel with the direction of plunger movement in the fitted syringe and is offset in relation to the centre line of said plunger.

5. A pump according to any one of Claims 1-3, **characterized** in that the screw is disposed generally along a centre line of the fitted syringe.

6. A pump according to any one of the preceding Claims, **characterized** in that the runner includes two mutually facing, generally flat and mutually parallel surfaces of which one has ridges and troughs whose periodicity corresponds to the pitch of the screw-thread and an inclination corresponding to the tangential direction of the screw-thread, whereas the other surface lacks ridges and troughs.

7. A pump according to Claim 2 and Claim 5, **characterized** in that the surface provided with ridges and troughs is so adapted and chosen in relation to the screw-thread, that the component of force which acts on said surface perpendicular to the direction of the screw as it rotates in the pump emptying direction is directed such as to move the syringe inwards and not towards the lid.

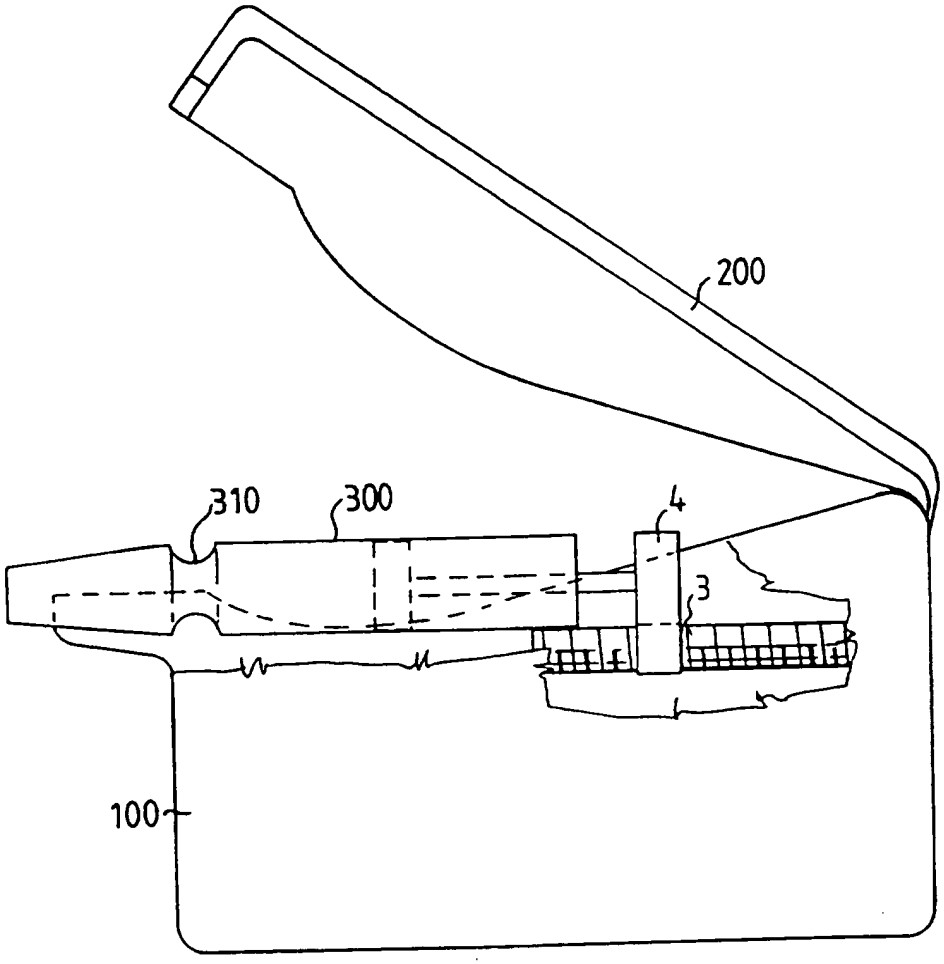

FIG.1

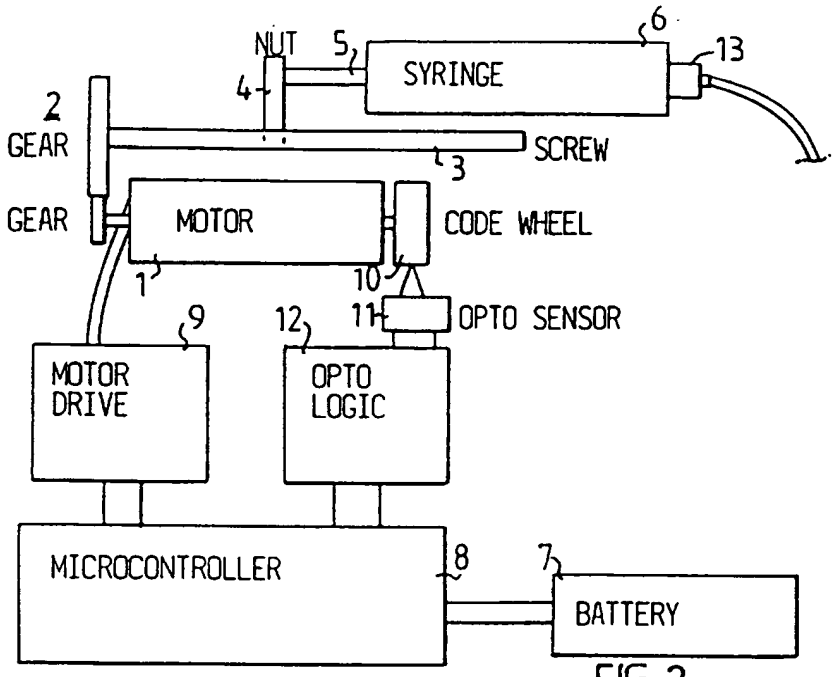

FIG. 2

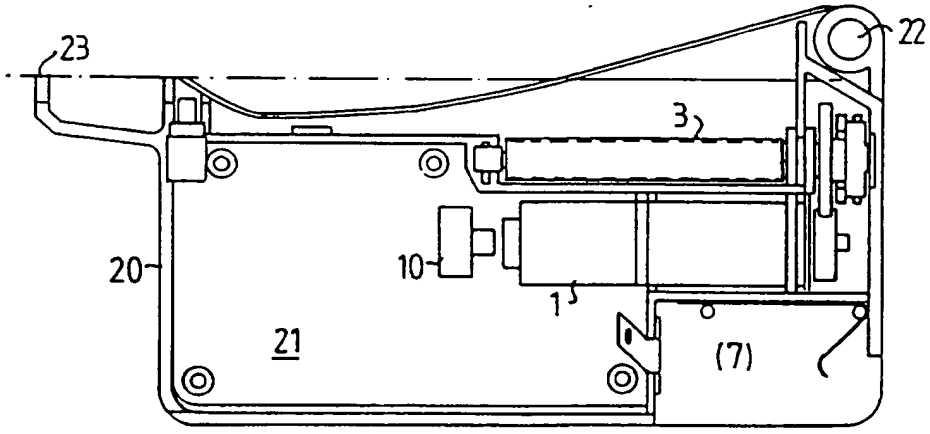

FIG. 3

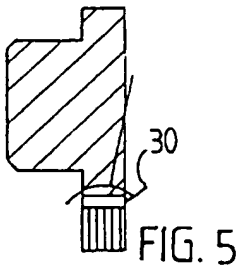

FIG. 5

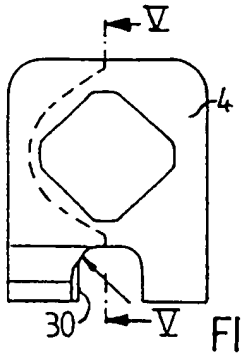

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/01344

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/145, A61M 1/02, A61M 1/14
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4544369 A (JAMES G. SKAKOON ET AL), 1 October 1985 (01.10.85), column 2, line 45 - column 3, line 9, claims 12-14, figures	1,4,5
Y	--	2,3,6,7
Y	US 4562751 A (CLYDE K. NASON ET AL), 7 January 1986 (07.01.86), column 16, line 20 - line 26, figures	2,3
	--	
Y	EP 0285403 A2 (BIONICA PTY. LIMITED), 5 October 1988 (05.10.88), figures 8,10, claim 22	6,7
	--	

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
22 February 1996	26.02.1996
Name and mailing address of the ISA/ Swedish Patent Offic Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Inger Löfgren Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/01344

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0388102 A2 (THE BOC GROUP PLC), 19 Sept 1990 (19.09.90), abstract -- --------	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

05/02/96

International application No.
PCT/SE 95/01344

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		CA-A- 1236740	17/05/88
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		US-A- 4919650	24/04/90
EP-A2- 0388102	19/09/90	NONE	